REMARKS

The following issues are outstanding in the pending application:

- Claims 1-15 and 17-22 are rejected under 35 USC 103.

1 and 18 have been amended in order to more clearly define the subject invention. Amended independent claims 1 and 18 now recite a method for forming a texturized proteinaceous meat analogue and the texturized proteinaceous meat analogue product in which a mixture is provided containing about 20 to 80% by weight edible proteinaceous materials, up to about 5% by weight of edible mineral binding and cross-linking compounds; and up to about 50% by weight of an edible humectant system consisting of a mixture of glycerol and glucose. The mixture is subject to mechanical pressure and heat sufficient to convert the mixture into a hot protein lava that is extruded to obtain a cohesive, texturized, extrudate slab or ribbon that forms the meat analogue product having a relative water activity of lower than about 0.8. No new material has been added as a result of the amendment.

35 USC 103

Claims 1-15 and 17-22 are rejected under 35 USE 103(a) a having subject matter unpatentable over WO 2000/69276 to Howsam in vie of U.S. Pat. No. 6,277,420 to Andersen et al. Applicant respectfully traverses this rejection.

Howsam is directed to a high moisture level texturized protein product (TPP) formed from non-animal protein in an extrusion cooking process in which the TPP closely resembles an animal protein product in texture and structure, such as flaked fish meat or shredded chicken meat. The Howsam TPP includes non-animal edible proteinaceous materials, edible mineral binding and cross-linking compounds and has a moisture content of between about 40-60%. The Howsam-type product is intended for use in canned foods and the product would be similar to sausage having a similar water content of between 40-60%, which results in a water activity of about 0.85 to 0.95. Thus, the Howsam TPP would have a water activity greater than 0.8. See the attached white paper titled "Water Activity: The Key to Pet Food Quality and Safety" by B. Carter and A. Fontana, Jr. Ph.D. www.decagon.com.

Andersen et. al is directed to a pet chew having an outer shell of natural or reformed rawhide and an inner cylinder of shelf-stable meaty filling set into a firm gel. The meaty filling includes fresh meat, dehydrated meat or meat by-products, a sweetener or combination of sweeteners (10-40%) and humectants such as glycerol, propylene glycol or sorbitol. A low water activity is desired to reduce migration of water from the filling to the outer shell.

Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), controls the consideration and determination of obviousness under 35 U.S.C. 103(a); *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1734-35, 167 L. Ed. 2d 705, 715 (U.S. 2007). The four factual inquires enunciated therein for determining obviousness are: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations.

In this case, neither the level of ordinary skill in the art, nor secondary considerations are at issue. However, in order to assess the scope and content of the prior art properly, a thorough understanding of the invention must be acquired by studying Applicant's claims and the specification. M.P.E.P. § 2141. Thus, the inquiry begins with construction of Applicant's claims, explained below. Next, when ascertaining the differences between the prior art and the claims at issue, both the invention and the prior art references as a whole must be considered, and ***all*** claim limitations must be considered when determining patentability of Applicant's invention. M.P.E.P. §§ 2141; 2143. When this is properly done in this case, as shown below, it becomes clear that differences exist that preclude obviousness. And finally, the test for obviousness requires identification of a reasonable basis for combining the claimed elements in the claimed fashion. *KSR*, 127 S. Ct. at 1741; M.P.E.P. §2143. As shown below, this requirement is not met in this case, and no *prima facie* case for obviousness is made.

Applying the proper test to this case begins with amended independent claims 1 and 18 which require at least "providing a mixture containing about 20 to 80% by weight edible proteinaceous materials selected from the group consisting of predetermined mixtures of defatted soy flour, soy meal, soy concentrate, cereal gluten and egg white powder, and up to about 50% by weight of an edible humectant system consisting of a mixture of glycerol and

glucose and thereafter converting the mixture into a hot protein lava that is extruded to obtain a cohesive, texturized, extrudate slab or ribbon that forms the meat analogue product having a relative water activity of lower than about 0.8."

The Howsam reference does not teach a mixture that includes an edible humectant system consisting of a mixture of glycerol and glucose and forming a meat analogue product having a relative water activity of lower than about 0.8. The Howsam reference teaches a high moisture level texturized protein product (TPP) that includes edible proteinaceous materials (which are substantially if not completely from non-animal protein sources) and edible mineral binding and cross-linking compounds that forms a texturized meat analogue product having a moisture content of between about 40-60% which results in a water activity greater than 0.8. In addition to not including the an edible humectant system consisting of a mixture of glycerol and glucose, the Howsam meat analogue product has a water activity greater that 0.8. In order to make a proper *prima facie* case for obviousness, all claim limitations must be accounted for. M.P.E.P. § 2143.03. This rejection fails to consider all elements of the claims and their meaning. Thus, the claims are erroneously rejected over the Howsam reference and Applicant respectfully requests the rejection be removed.

Just as there is no teaching of a texturized meat analogue product that includes an edible humectant system consisting of a mixture of glycerol and glucose and has a relative water activity of lower than about 0.8, there is also no rational basis provided in the Action for combining the claimed elements in the claimed fashion, as the law requires. *KSR*, 127 S.Ct. at 1741. The Action states that the reason for combining the elements is that it would be obvious to one of ordinary skill in the art to modify the teachings of Howsam by adopting and using the teachings of Andersen et al. to receive the benefit of a product having reduced water activity and resisting drying out. However, the Andersen reference is directed a pet chew having an outer shell of natural or reformed rawhide and an inner cylinder of shelf-stable meaty filling set into a firm gel. The meaty filling includes fresh meat, dehydrated meat or meat by-products, a sweetener or combination of sweeteners (10-40%) and humectants such as glycerol, propylene glycol or sorbitol. The pet chew of Andersen is a substantially different product than a texturized proteianceous meat analogue product which is formed in a substantially different way. As described in the subject specification, reducing the water activity in the Howsam product is not a simple matter. See below:

[0009] "A common way to reduce water activity while maintaining product texture is to incorporate one or more humectant materials in the formulation. However, for the type of product described in WO 00/69276, i.e. high-moisture extruded TPP, it has been found that many of the common humectant systems do not provide a solution to the problem. The incorporation of sugars at 12% by mass of the formulation, as used in other semi-moist pet foods, tended to cause blockages and product burning in the high-shear twin-screw extruders that are necessary for the manufacture of this type of product.

[0010] – "Similarly, the use of a lower viscosity humectant material, such as a sugar solution, resulted in an inability of the process to provide the correct 'striated' texture for the product. This is because lower viscosity / higher fluid content feedstocks are not capable of producing a textured extrudate, especially for this type of extrusion."

[0011] – "Other liquid humectants, such as propylene glycol, are available for extending the shelf life of such TPP products. However, these materials also tend to compromise the texture of the product when added at the levels necessary to produce the shelf-life extension sought. Furthermore, propylene glycol is not suitable for TPP that is to be fed to felines, as it is toxic for these animals. It also tends to produce a flavour taint that is undesirable."

Thus, as described above, the addition of 10-40% of sweeteners to the Howsam product will not produce the product recited in claims 1 and 18. Nor will the addition of Andersen's laundry list of humectants to the Howsam product produce the product recited in claims 1 and 18. The discussion in the subject specification and replicated above, provides evidence to the contrary that there is a reasonable expectation of success to produce the claimed invention by modifying the teaching of Howsam with the teachings of Andersen et al. Further, as a meat analogue (also called meat substitute or mock meat) is a food product that approximates the aesthetic qualities and/or chemical characteristics of certain types of meat, any alternation in the appearance of the Howsam product due to the modifications taught by Andersen will result in a product different from the subject invention as recited in amended claims 1 and 18. "A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art." *KSR* 127 S.Ct. at 1741 (citing United States v. Adams, 383 U.S. 39 (1966)). Therefore, Applicant respectfully submits that independent amended claims 1 and 18 are not obvious.

If an independent claim is non-obvious under 35 U.S.C. 103, than any claim depending therefrom is by definition non-obvious. Applicant respectfully submits that claims 2-15, 17 and 19-22 depend at least in part from independent amended claim 1 or claim 18. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 1-15 and 17-22 under 35 USC 103(a) as having subject matter

unpatentable over WO 2000/69276 to Howsam in vie of U.S. Pat. No. 6,277,420 to Andersen et al.

CONCLUSION

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03130US0 from which the undersigned is authorized to draw.

Dated: March 4, 2008

Respectfully submitted,

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Water Activity: The Key to Pet Food Quality and Safety

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Introduction

Pet food safety is an important issue in the Pet Food and Feed Industries as a result of several high profile product recalls that have recently occurred. With the anticipation of new government regulations and a need to ensure consumer confidence, manufacturers need tools to ensure product safety and quality. Microbial spoilage is one of the most common reasons for product recalls. Water activity has been used in food production for decades as an effective way of determining if a food is safe from microbial growth. It is used effectively in the Pet Food Industry and should be an integral part of manufacturing and any future regulations (Lowe and Kershaw, 1995).

In fact, water activity has been an important parameter in commercial pet foods since the late 1960's. Soon after Scott (1957) showed that microorganisms have a limiting water activity level below which they will not grow, scientists were looking for other practical application of a_w. One of the first products fully developed using water activity technology was "Gainesburgers" made by General Foods Corp. Gainesburgers were an intermediate moisture dog food that were promoted as "the canned dog food without the can". Quaker Oats Company followed in the mid-1960's by introducing a shelf-stable, intermediate-moisture marbled meat pet food. Water activity technology provided the means to form a soft, elastic, marbled product resembling meat. This highly successful dog food is reported to have generated more profit per square foot of display shelf space than any other product.

Pet food and animal feeds need to be nutritious, safe, and stable at a specified shelf life. Just like human food, pet diet components are susceptible to microbial, chemical, physical, and insect spoilage. Water activity (a_w) is one of the most important parameters in preservation, safety, and quality. Water activity is a very practical tool in developing and producing nutritious, safe, and stable pet food because it is critical for microbial growth, texture, flavor, chemical reactivity (such as browning or lipid oxidation), or enzyme activity.

Moisture Analysis

Traditionally, discussions on controlling the water in pet food products have focused on moisture content or the total amount of water in a system. Moisture content provides valuable information about product quality, but it is only one part of a complete moisture analysis. Water activity is another important moisture measurement that defines the energy or 'availability' of water in a product. While both measurements are important, water activity provides the most valuable information about product safety and quality.

Water activity represents the energy status of the water in a product. It is based in thermodynamics and is defined as the vapor pressure of water (p) over a sample divided by the vapor pressure of pure water (p_o) at a given temperature. Though not scientifically correct, it may help to picture water activity as the amount of 'bound' or 'available' water in pet food. It is not determined by how much water is present, but is a comparison of how much the water in pet food resembles and behaves like pure water. Water activity values represent a scale that ranges from 0 (bone dry) to 1.0 (pure water).

Microbial Growth

The water activity concept has served microbiologists and food technologists for decades and is the most commonly used criterion for food safety and quality. Microorganisms have a limiting water activity below which they cannot grow (Beuchat, 1983;Scott, 1957). Water activity, not moisture content, determines the lower limit of "available" water for microbial growth. Table 1 shows the growth limit for the common spoilage organisms. These values were established under ideal conditions for microbial growth for all other growth factors such as pH and temperature. In other words, they represent the true lower water activity limit for growth under a worst case scenario. The water activity level that limits the growth of the vast majority of pathogenic bacteria is 0.90, a water activity of 0.70 is the lower limit for spoilage molds, and the limit for all microorganisms is 0.60.

Table 1. Water activity lower limit for growth for common spoilage organisms.

Microorganism	Minimum a_w	Microorganism	Minimum a_w
Clostridium botulinum E	0.97	*Penicillum expansum*	0.83
Pseudomonas fluorescens	0.97	*Penicillum islandicum*	0.83
Escherichia coli	0.95	*Debarymoces hansenii*	0.83
Clostridium perfringens	0.95	*Aspergillus fumigatus*	0.82
Salmonella spp.	0.95	*Penicillum cyclopium*	0.81
Clostridium botulinum A, B	0.94	*Saccharomyces bailii*	0.80
Vibrio parahaemoliticus	0.94	*Penicillum martensii* *Penicillum chrysogenum*	0.79
Bacillus cereus	0.93	*Aspergillus niger*	0.77
Rhizopus nigricans	0.93	*Aspergillus ochraceous*	0.77
Listeria monocytogenes	0.92	*Aspergillus restrictus*	0.75
Bacillus subtilis	0.91	*Aspergillus candidus*	0.75
Staphylococcus aureus (anaerobic)	0.90	*Eurotium chevalieri*	0.71
Saccharomyces cerevisiae	0.90	*Eurotium amstelodami*	0.70
Candida	0.88	*Zygosaccharomyces rouxii*	0.62
Staphylococcus aureus (aerobic)	0.86	*Monascus bisporus*	0.61

(adapted from Beuchat 1983)

Since bacteria, yeast, and molds require a certain 'availability' of water to support growth, drying pet food below a critical a_w level provides an effective means to control microbial growth. Water may be present, even at higher content levels than normally acceptable in pet food, but if its water activity is sufficiently low, the microorganisms cannot utilize the water to support their growth. This 'desert-like' condition creates an osmotic imbalance between the microorganisms and the local environment and consequently, the microbes become dormant or die.

Table 2 shows a survey of the water activity and moisture content of several different samples of different commercial pet foods. These water activities were measured using an AquaLab chilled mirror water activity instrument (Decagon Devices, Inc). All samples were sliced small enough to fit in the instrument's sample cup and the tests were run in duplicate. These results indicate a range of water activity/moisture content combinations depending on the formulation of the pet food product. A comparison of the values in Table 2 and Table 1 gives an indication of the susceptibility of these products to spoilage based on their water activity. Comparing the two tables also illustrates why moisture content is not a good indicator of susceptibility to microbial spoilage. For example, intermediate pet food 1 will support mold growth while intermediate pet food 4 cannot, even though their moisture contents are essentially the same. Intermediate pet food 4 would have the added benefit of not requiring additional preservatives to prevent mold spoilage.

While both intermediate moisture pet food 1 and 2 will support mold growth, neither product will support the growth of pathogenic bacteria. Consequently, neither product would be considered potentially hazardous if regulated by the 2005 Food Code. However, intermediate moisture pet food 2 has the higher moisture content even though it has the lower water activity. This is accomplished by manipulating the formulation using water lowering ingredients called humectants. Some commonly used humectants include salt, sugar, propylene glycol, glycerol, etc.. A higher moisture level can be advantageous for both production and textural qualities.

Product Quality

Water activity is also an indicator of pet food physical properties and stability. Controlling water activity maintains proper structure, texture, stability, and density (Katz and Labuza, 1981). A critical water activity can be identified below which pet food will maintain its hard crunch. Above this critical water activity, the pet food particles are plasticized and soften. Conversely, intermediate moisture pet foods that have a soft texture must be at high enough water activities to maintain the soft texture but low enough to prevent spoilage. Consequently, knowledge of the water activity of pet food as a function of moisture content and temperature is essential during processing, handling, packaging and storage to maintain proper textural qualities.

Table 2. Water activities of common pet food products as measured using Decagon Devices' AquaLab chilled mirror water activity instrument.

Product	Water Activity	Moisture Content (% d.b.)
Moist Canned Pet Food 1	0.994	79.6
Moist Canned Pet Food 2	0.830	24.0
Intermediate Moisture Pet Food 1	0.823	13.70
Intermediate Moisture Pet Food 2	0.791	14.40
Intermediate Moisture Pet Food 3	0.679	8.43
Intermediate Moisture Pet Food 4	0.669	13.0
Intermediate Moisture Pet Food 5	0.525	9.21
Dry Pet Food 1	0.493	8.59
Dry Pet Food 2	0.459	7.79
Dry Pet Food 3	0.236	4.40

Because water activity is a measure of the energy status of the water, differences in water activity are the driving force for moisture migration. By definition, water activity dictates that moisture will migrate from a region of higher a_w to a region of lower a_w, but the rate of migration depends on many factors. Many pet foods are multi-component products with heterogeneous regions. If these regions are at different water activities, water will migrate between the components until they reach an equilibrium water activity, regardless of their moisture contents (Brandt, 1996;Katz and Labuza, 1981). For example, if two components of a multi-component pet food product both have 15% moisture content but are different water activities, moisture will be exchanged, even though their moisture contents are the same. This moisture migration could lead to textural or microbial spoilage problems.

There are a number of products on the market with multi-textured characteristics that use water activity. These products combine a hard, dry-baked pet food and a soft, moist pet food. The hard, dry component has the advantage of teeth cleaning, but is less palatable than a soft, moist food. The soft, moist component may be highly palatable, but lacks the abrasive teeth cleaning property. When the two components are mixed, they equilibrate to a common equilibrium water activity during storage. This equilibrium a_w must allow the dry component to remain hard and crunchy while leaving the soft component moist and tender

Measurement of Water Activity

Water activity is measured by equilibrating the liquid phase water in the sample with the vapor phase water in the headspace of a closed chamber and measuring the vapor pressure of the headspace. New instrument technologies have vastly improved speed, accuracy and reliability of measurements. Two different types of water activity instruments are commercially available. One uses chilled mirror dewpoint technology while the other utilizes relative humidity sensors that change electrical resistance or capacitance; each has advantages and disadvantages. The methods vary in accuracy, repeatability, speed of measurement, stability in calibration, linearity, and convenience of use.

In a chilled mirror dewpoint system, a sample is placed in a sample cup which is then sealed against a sensor block. Inside the sensor block is a dewpoint sensor, an infrared thermometer, and a fan. The dewpoint sensor measures the dewpoint temperature of the air and the infrared thermometer measures the sample temperature. From these measurements, the relative humidity of the headspace is computed as the ratio of dewpoint temperature saturation vapor pressure to saturation vapor pressure at the sample temperature. When the water activity of the sample and the relative humidity of the air are in equilibrium, the measurement of the headspace humidity gives the water activity of the sample. The fan is to speed equilibrium and to control the boundary layer conductance of the dewpoint sensor.

The major advantages of the chilled mirror dewpoint method are speed and accuracy. Chilled mirror dewpoint is a primary approach to measurement of relative humidity based on fundamental thermodynamic principles. Chilled mirror instruments make accurate ($\pm 0.003a_w$) measurements in less than 5 minutes. Since the measurement is based on temperature determination, calibration is unnecessary, but running a standard salt solution checks proper functioning of the instrument. If there is a problem, the mirror is easily accessible and can be cleaned in a few minutes. For some applications, fast readings allow manufacturers to perform at-line monitoring of a product's water activity.

Other water activity instruments use resistance or capacitance sensors to measure relative humidity. These sensors are made from a hygroscopic polymer and associated circuitry that gives a signal relative to the equilibrium relative humidity (ERH). Commercially available instruments measure over the entire a_w range with an accuracy of $\pm 0.015 a_w$. Since these instruments relate an electrical signal to relative humidity, the sensor must be calibrated with known salt standards. In addition, the ERH is equal to the sample water activity only as long as the sample and sensor temperatures are the same. Accurate measurements require good temperature control or measurement. Advantages of capacitance sensors include simple design and inexpensive implementation.

Conclusion

Water activity is an effective tool for maintaining the stability, quality, and safety of pet food. In addition, in the intermediate moisture region, which includes a majority of the pet food, changes in moisture content that are undetectable due to the limited accuracy of moisture content analyses can result in large changes in water activity and consequently, changes in stability. This can be disconcerting when pet food is dried to a moisture content specification and stability changes suddenly occur even though a moisture content change is not detected. These stability changes can be predicted if a water activity specification is used. Water activity is a fast, inexpensive, and accurate way of assuring the quality and safety of pet food. It can easily be incorporated by any production facility or quality control laboratory.

The pet food and feed industries have long used water activity to create novel products and predict shelf life, safety, and quality. Determination of water activity during manufacture allows tight control of pet foods and feedstuffs found to be at high risk for deterioration. Without the use of water activity, the pet food industry would have a hard time developing novel new products or producing nutritious, high quality, stable food.

Reference List

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